NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

January 29, 2002

NFPA COMMENTS

Re: Docket No. 00D-1543
Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Glossary of Terms

Dear Sir or Madam:

The National Food Processors Association (NFPA) is the principal scientific trade association representing the $500 billion food processing industry. With three laboratory centers, NFPA is the leading authority on food science and safety for the food industry. For more than 90 years, the food industry has relied on NFPA for government and regulatory affairs representation, scientific research, technical services, education, communications, and crisis management.

NFPA's scientists, government affairs, regulatory, and communications experts, provide assistance to member companies and work to ensure that laws and regulations governing the food industry have a sound scientific foundation.

NFPA offers the following comments on Glossary of Terms.

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1. Overall, a glossary of terms is important for consistency and clarity, however, there appears to be an opportunity to consolidate terms and definitions into a master list. The Glossary of Computerized System and Software Development Terminology, August 1995, U.S.FDA, ORA, offers the chance for simplifying and consolidating. We would suggest that FDA consider establishing one master glossary, to envelope all terms as they relate to the electronic world (regulations and guidance). In addition, we would also suggest that as new terms are introduced in new documents/regulations that they be initially defined in the original document/regulation and then be included into this master glossary for global reference.
   For example, 21 CFR Part 11 closed system, the definition appears in the regulation, it can be added to the master glossary, and can be referenced back to the original regulation if included in the guidance documents. If the definitions are expanded on or interpreted for clarity, that too can be accomplished within the guidance document itself.

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2. There is confusion in the food industry on what constitutes an electronic record subject to Part 11. In reviewing the terms defined in the guideline, we feel that further clarification is required which probably impacts the scope and should be considered in the context of the scope guidance document. Required records, per the predicate rules, are captured in many ways within the food industry, some examples include:

    - Record keeping sheet of paper on which all information is entered by hand at the time the information is gathered and is signed by hand by the information gatherer and reviewed and signed by hand by the supervisor within one working day.
    - Record keeping is done on a form with pre-formatted information, which is kept in a computer. The information gatherer types the information into the computer at the time the information is gathered and the control system generates data. The information gathered electronically and information typed manually are printed as soon as a group is read. The form is signed by the information gatherer and reviewed and signed by the supervisor within one working day.
    - Record keeping is done on a form with pre-formatted information, which is kept in a computer. All the information is gathered electronically and the data gathered is entered into the form by a computer. The individual responsible for the data acquisition verifies the data entered. At the end of the day, the form is printed out and is signed by hand by the individual responsible for the information gathered and reviewed and signed by the supervisor within one working day.

In all these cases, the record is not an official record for FDA compliance until reviewed and signed by the appropriate authorities.
The examples above indicate what the food industry current practices are and what has been accepted as paper records. Although the information may be in part or whole captured electronically, the "official" record is a paper record that has been reviewed and signed and stored away in a file cabinet with the remaining required production records that assures no public health hazard by assuring adequacy of the process. The computer system can be viewed as incidental to the creation of the record, since the records are being kept on paper, not electronically.

3. Comments on Glossary Terms:

Reference term	Proposed Change	Comment
Computer Systems Validation	Suggest replacing "...user needs and intended uses, and that all requirements can be consistently fulfilled" with "the users requirement specifications."	"All requirements" and current users needs may not always be satisfied due to the technology that was employed at the time of installation. Hence, alternative control and monitoring mechanisms should be sufficient for objective evidence.
Electronic Record	Suggest adding, "....by a computer system, once it has been associated with an electronic "review" signature."	Food industry required records are all reviewed and signed before becoming "official" records. Hence, required records that are electronic records coupled with an electronic review and signature should be the only records subject to Part 11.
Change Control	Suggest adding this definition: Objective evidence that a mechanism is in place where in which considerations are evaluated to determine the potential impact of changes on systems that have been operating as intended.	Compliance definition required to support 11.10(k)(2).
Legacy Systems	Add the following definition, Computer systems that were in place prior to enactment of Part 11	

NFPA values the effort that the Agency is putting toward clarification of 21CFR Part 11 and appreciates the opportunity to share the food industries main concerns so that a workable solution is achieved and the food safety and public health safety are preserved.

Thank you for providing this opportunity to comment.

Sincerely,

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Sr. Scientist

Allen Matthys, Ph.D.
V.P. Federal and State Regulations

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